

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
ACD Whole Blood	Not applicabledo	21 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
CPD Whole Blooddodo	Do.
CPDA-1 Whole Blooddodo	35 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
Heparin Whole Blooddodo	48 hours from date of collection, provided labeling recommends storage between 1 and 6 °C.
Yellow Fever Vaccinedo	1 year (–20 °C or colder).	1 year, provided labeling recommends storage at 5 °C or colder.

(d) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of a supplement of the product license, issued by the Director, Center for Biologics Evaluation and Research (HFB-1).

[50 FR 4134, Jan. 29, 1985, as amended at 51 FR 15607, Apr. 25, 1986; 51 FR 19750, June 2, 1986; 52 FR 37450, Oct. 7, 1987; 53 FR 12764, Apr. 19, 1988; 55 FR 11014, Mar. 26, 1990; 59 FR 49351, Sept. 28, 1994; 62 FR 15110, Mar. 31, 1997]

Subpart G—Labeling Standards

§ 610.60 Container label.

(a) *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:

- (1) The proper name of the product;
- (2) The name, address, and license number of manufacturer;
- (3) The lot number or other lot identification;
- (4) The expiration date;
- (5) The recommended individual dose, for multiple dose containers.
- (6) The statement: "Caution: Federal law prohibits dispensing without prescription," for prescription biologicals.

(b) *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.

(c) *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name

of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.

(d) *No container label.* If the container is incapable of bearing any label, the items required for a container label may be omitted, provided the container is placed in a package which bears all the items required for a package label.

(e) *Visual inspection.* When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.

[38 FR 32056, Nov. 20, 1973, as amended at 47 FR 22518, May 25, 1982]

§ 610.61 Package label.

The following items shall appear on the label affixed to each package containing a product:

- (a) The proper name of the product;
- (b) The name, address, and license number of manufacturer;
- (c) The lot number or other lot identification;
- (d) The expiration date;
- (e) The preservative used and its concentration, or if no preservative is used and the absence of a preservative is a safety factor, the words "no preservative";
- (f) The number of containers, if more than one;
- (g) The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency,